



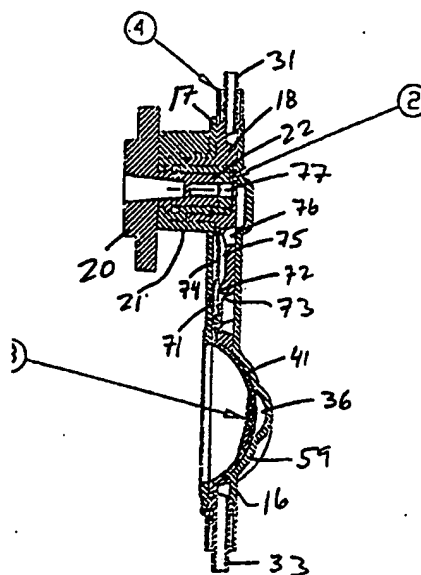
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(54) Title: CASSETTE FOR INTRAVENOUS-LINE FLOW-CONTROL SYSTEM

(57) Abstract

A cassette for controlling the flow of IV fluid from a patient to a source. The cassette preferably includes, along the fluid passage through the cassette, first and second membrane-based valves (6, 7) on either side of a pressure-conduction chamber (50), and a stopcock-type valve (20). The stopcock valve is preferably located downstream of the second membrane-based valve (7), which is preferably located downstream of the pressure-conduction chamber (50). The stopcock control valve preferably has two rigid cylindrical members (22, 220) with complementary surfaces, wherein one member includes a tapered groove (231) defined on its complementary surface. The two complementary surfaces define a space therebetween, instead of having an interference fit, and a resilient sealing member (25) is disposed in this space. When the first and second rigid members are in an open position with respect to each other, the sealing member defines an aperture (251) through which fluid communication is provided between the fluid-path portions (23, 24) defined respectively by the two rigid members. When the first and second rigid members are in the closed position with respect to each other, the sealing member provides a seal preventing flow between the fluid-path portions. The membrane defining the valving chamber of the second membrane-based valve (7) is preferably large and resilient, so that the valving chamber (75) may provide a supply of pressurized intravenous fluid to the patient, when the valve is closed and the stopcock valve provides a restriction downstream of the valve. The pressure-conduction chamber (50) preferably has a membrane (41) that is stable in the empty-chamber position but relatively unstable in the filled-chamber position.



SECTION A-A

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CASSETTE FOR INTRAVENOUS-LINE FLOW-CONTROL SYSTEM

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DESCRIPTION

Technical Field

The present invention relates to apparatus and methods for controlling flow
10 through an intravenous line.

Summary of the Invention

The invention is directed to a cassette for controlling the flow of IV fluid from a patient to a source. The cassette preferably includes, along the fluid passage through the
15 cassette, first and second membrane-based valves on either side of a pressure-conduction chamber, and a stopcock-type valve. The stopcock valve is preferably located downstream of the second membrane-based valve, which is preferably located downstream of the pressure-conduction chamber.

It is preferred to use a stopcock control valve of the type having a first rigid
20 member (preferably cylindrical) having a first surface (preferably the cylinder's circumferential surface), and a second rigid member (also preferably cylindrical) having a second surface that complements the first surface. The first rigid member defines a first fluid-path portion with a first terminus at the first surface, and the second rigid member defining a second fluid-path portion with a second terminus at the second surface. The
25 first terminus preferably includes a groove defined on the first surface, the groove tapering from a large cross-sectional area to a small cross-sectional area. The first and second rigid members are capable of being rotated with respect to each other from a fully open position continuously through partially open positions to a closed position.

In an improved version of this type of stopcock valve, according to the present
30 invention, the first and second surfaces define a space therebetween, instead of having an interference fit typical of prior-art valves. Also, the improved valve includes a resilient

sealing member disposed in the space between the first and second surfaces and extending from the second surface to the first surface. The sealing member defines an aperture through which fluid communication is provided between the first and second fluid-path portions when the first and second rigid members are in an open position with respect to each other. The sealing member is sealingly mounted to the second surface so that, when the first and second rigid members are in the closed position with respect to each other, the sealing member provides a seal preventing flow between the first and second fluid-path portions. The sealing member is located with respect to the groove such that, when the first and second rigid members are in a partially open position with respect to each other, fluid flowing between the first and second fluid-path portions flows through the groove as well as the sealing member's aperture. The improved valve further includes seal means disposed with respect to the space defined by the first and second surfaces for preventing flow of fluid out of the space except through the first fluid-path portion. Preferably, the seal means includes an O-ring made of resilient material disposed around the second rigid member's circumference. It is also preferred that the sealing member and the O-ring be formed from a single integral piece of resilient material.

Preferably, the groove, when the first and second members are in at least one partially open position with respect to each other, extends beyond two sides of the sealing member, so that fluid can flow through the sealing member's aperture and in two different directions in the groove.

It is also preferred that the valve be made by molding a resilient material about and to the second rigid member so as to form an aperture sealing member about the port on the complementing surface of the second rigid member, and then assembling the first and second rigid members, which are preferably molded out of rigid material. so as to bring the complementing surfaces adjacent each other and so that the sealing member is urged against the complementing surface of the first rigid surface.

In a preferred version of the cassette, which is primarily made out of rigid material, the membrane for the second membrane-based valve is disposed adjacent the housing, such that the rigid housing and the membrane define a valving chamber. One passage enters the valving chamber at a first mouth located at the end of a protrusion of the rigid housing into the valving chamber towards the membrane, and the valve may prevent the

flow of fluid therethrough when the membrane is forced against the first mouth, by the control unit. The control valve restricts the flow of intravenous fluid from the valving chamber to the patient, since it is located downstream of the valving chamber. The membrane defining the valving chamber is preferably large and resilient, so that the

5 valving chamber may provide a supply of pressurized intravenous fluid to the patient, when the first mouth is sealed closed and when there is a restriction downstream of the valving chamber.

For the pressure-conduction chamber, a membrane is preferably disposed adjacent the rigid housing, so as to define a pressure-conduction chamber, wherein the rigid

10 housing portion that defines the pressure-conduction chamber is generally dome-shaped. The membrane has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is at its smallest volume, and in which position the second membrane rests against the rigid housing and assumes the dome shape of the

15 rigid housing. The second membrane preferably has a structure causing the membrane to be stable in the empty-chamber position but relatively unstable in the filled chamber position. The rigid housing and the second membrane in the empty-chamber position preferably define an unobstructed fluid passageway through the pressure-conduction chamber from the first to the second pressure-conduction chamber mouth. Preferably, the

20 membrane has a structure that causes the second membrane, when its at its full-chamber position, to collapse in the region of the pressure-conduction chamber's outlet mouth before collapsing nearer the inlet mouth. This structure helps force bubbles in the fluid upward toward the inlet mouth and the IV fluid source during a bubble-purge cycle.

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Brief Description of the Drawings

FIG. 1 shows a top view of a cassette according to a preferred embodiment A the present invention.

FIGS. 2 and 3 show front and bottom views respectively of the cassette of FIG. 1.

FIG. 4 shows a control unit for receiving and controlling a cassette, such as the

30 cassette of FIGS. 1 - 3.

FIG. 5 shows a cross-section of the cassette of FIGS. 1 - 3.

FIG. 6 shows a rear view of the cassette and shows the fluid paths through the cassette.

FIG. 7 shows a front view of the middle rigid panel of the cassette of FIGS. 1 - 3.

FIGS. 8 and 9 show side and rear views respectively of the middle panel of FIG. 7.

5 FIG. 10 shows a partial cross-section of the middle panel of FIG. 7.

FIG. 11 is a cross-sectional detail of the control valve of the cassette according to a preferred embodiment of the invention.

FIG. 12 shows a side view of an outer cylinder (a valve-seat member) having rigid and resilient elements that may be used in the control valve.

10 FIG. 13 shows a cross-sectional view of the cylinder of FIG. 12.

FIG. 14 depicts the relationship between the aperture of the FIG. 12 cylinder and the groove used in the control valve.

FIG. 15 shows a cross-sectional view of the membrane used in the pressure-conduction chamber of the present invention.

15 FIGS. 16 and 17 show front and rear views respectively of the FIG. 15 membrane.

FIG. 18 shows a front view of the membrane used in the valve located downstream of the pressure-conduction chamber and upstream of the control valve.

FIG. 19 shows a cross-section of the FIG. 18 membrane.

FIG. 20 is a schematic representing how the compliant membrane of FIG. 18 may
20 be used to regulate the pressure of fluid to the patient.

FIG. 21 is a graph depicting the advantage of using a compliant membrane such as that shown in FIG. 18.

FIGS. 22 and 23 depict the preferred shape of the inlet valve to the pressure conduction chamber.

25 FIG. 24 shows a cross-sectional view of the inlet valve to the pressure conduction chamber.

FIG. 25 shows a preferred arrangement of teeth around the circumference of the control wheel.

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Detailed Description of Specific Embodiments

The present invention includes a cassette for use in a system for controlling the

flow of IV fluid to a patient, along the lines of the cassettes disclosed in U.S. Patents Nos. 5,088,515 and 5,195,986. A preferred embodiment of the cassette is depicted in FIGS. 1 - 3, which respectively depict top, front and bottom views of the cassette. The cassette is used in a control unit, which uses pressure, preferably pneumatic pressure, for controlling the actuation of valves and the urging of fluid into and out of a pressure-conduction chamber. In addition to performing the function of a pump urging fluid through the IV line, the pressure-conduction chamber can measure the amount of IV fluid being delivered to the patient as well as detect the presence of bubbles in the IV fluid in the pressure-conduction chamber. FIG. 4 depicts a preferred version of a control unit 10. Control unit 10 has a user-interface panel 103 containing a key pad and a display so that the status of the IV fluid delivery may be monitored and modified by medical personnel. The cassette is slipped behind door 102, and by turning handle 101 the door is pressed against the cassette, which in turn is then pressed against the main housing of the control unit 10. The main housing 104 preferably includes mechanical means for actuating membrane-covered valves and for applying a pressure against the membrane of the pressure-conduction chamber. The main housing 104 also includes means for turning the control wheel of the cassette.

Referring to FIG. 2, the main components of the preferred embodiment of the cassette are a first membrane-based valve 6, a pressure-conduction chamber 50, a second membrane based valve 7 and a stopcock-type control valve 20. Valve 6 controls the flow to the pressure-conduction chamber 50 from the inlet 31 to the cassette, which is connected to an IV line, which in turn is connected to a source of IV fluid. The second membrane-based valve 7 and the control valve 20 together are used to control the flow of fluid from the pressure-conduction chamber 50 to the outlet to the cassette 33, which is connected to the IV line leading to the patient.

The rigid housing 15 of the cassette is made primarily from three rigid panels. A front panel 17, a middle panel 18, and a rear panel 16, all three of which can be seen in FIGS. 1 and 3. The front panel is preferably molded integrally with the outer collar 21 of the control valve 2. The wheel 20 of the control valve 2 preferably includes ribs 281 and/or teeth mounted along the circumference 29 of the knob 20. (FIG. 25 shows a preferred arrangement of teeth around the circumference 29 of the control knob 20.) The

teeth and/or ribs 281 may be engaged by the main housing 104 of the control unit 10, so that the control unit 10 may change the resistance that the control valve 2 exerts on the IV fluid passing through the valve.

The cassette may also be used without the control unit 10. In that case, the control wheel 20 may be turned by hand. When disengaged from the control unit 10, the membrane of the pressure-conduction chamber 50 is preferably collapsed so that it rests against the rigid rear wall 59 of the pressure-conduction chamber 50. With the membrane in this collapsed state, IV fluid may still easily flow through the pressure-conduction chamber 50 through a raised portion 35 of the rear wall 59. This raised portion 35 defines a conduit 36 leading from the inlet mouth of the pressure conduction chamber 50 to the outlet mouth of the pressure conduction chamber, as can be seen in FIG. 4. FIG. 6 shows the fluid paths leading through the cassette. As noted above, fluid enters the cassette through the inlet 31, whence it flows through a fluid path to valve 6. The fluid then enters the valving chamber of valve 6 through a port 62. The outlet port 61 is preferably mounted on a protrusion so that pressure from the pressure-conduction chamber 50 is less likely to force the membrane to lift from the outlet valve 61. From valve 6 the fluid passes to the inlet mouth 56 of the pressure-conduction chamber 50. The pressure-conduction chamber is seen in the cross-sectional view of FIG. 5. A membrane 41 allows pressure from the control unit 10 to be applied to the fluid in the pressure-conduction chamber 50 without the fluid coming into contact with the control unit 10. When the membrane 41 is in its collapsed position resting against rigid wall 59, as shown in FIG. 5, fluid can still pass from inlet valve 56 through conduit 36 to the outlet valve 57. After passing through the pressure-conduction chamber 50, the fluid flows to the second membrane-based valve 7, which included an inlet mouth 73, which is mounted on a protrusion like the outlet mouth of the first membrane-based valve 6. The second membrane-based valve's inlet mouth 73 and the protrusion 72 on which it is mounted can be seen in the cross-sectional view of FIG. 5. Like the outlet mouth 61 of the first membrane-based valve, the inlet mouth 73 may be closed by the application of pressure by the control unit 10 on a membrane; the portion of the membrane 71 that closes off the inlet valve 73 can be seen in FIG. 5. After passing through the outlet mouth 76 of the second membrane-based valve, the fluid passes to the inlet 77 of the stopcock-type control

valve, which inlet can be seen in both FIGS. 5 and 6. After passing through the control valve and the fluid path 78 exiting from the control valve, the fluid passes to the outlet of the cassette 33 and to the IV line leading to the patient.

FIG. 7 shows a front view of the rigid middle panel 18 of the cassette, and FIG. 8 shows a side view of the middle rigid panel 18. The middle rigid panel 18 defines the cassette inlet 31 and outlet 33, a circumferential portion of the pressure-conduction chamber 50, and the inlet and outlet ports, 62, 73, 61 and 76, of the two membrane-based valves 6 and 7. The protrusions 63 and 72 of the ports 61 and 73 can also be seen in FIG. 7. FIG. 9 shows a rear view of the middle rigid portion shown in FIGS. 7 and 8. The ports 61, 62, 73, 76 can also be seen in FIG. 9. FIG. 10 shows a partial cross-section of the middle rigid portion. The cross-section shows the outer collar 21 of the control valve, which is integrally molded with the rest of the middle rigid portion. The outer collar 21 defines a hollow area 22 and a fluid path 23 leading from the hollow area 22.

FIG. 11 shows a cross-section of an assembled control valve 2 that may be used in a cassette according to the present invention. Just inside of the outer collar 21 is a valve-seat member 22 fixedly attached to the outer collar 21 so that the valve-seat member 21 does not rotate with respect to the rest of the cassette. The valve-seat member 21 is depicted in greater detail in FIG. 12 and in cross-section in FIG. 13. The valve-seat member 22 also defines a hollow area, which accepts the shaft 220 of the control wheel 20, so that the control wheel's shaft 220 rotates with the control wheel 20. The valve-seat member 22 is comprised mostly of rigid material, but importantly it also includes molded-over resilient material, which is used to form sealing O-rings. This resilient material forms an O-ring 26 around the base of the valve-seat member 22; the rigid portion of the base defines a passage 222, connecting the valve inlet 77 to passage 24. The resilient material 25 also provides a seal around an aperture 251 in the circumferential surface of the member 22. At the end of the member 22 opposite the inlet passage 222 is an inner O-ring 27 which forms the seal between the control wheel's shaft 220 and the valve-seat member 22. The O-ring 26 around the exterior circumference of the base provides a seal between the outer circumferential wall of the valve-seat member 22 and the inner circumferential wall of the outer collar 21. Likewise, the O-ring 25 around the circumferential port 251 may provide a seal between the outer circumferential wall of the

valve-seat member 22 and the inner circumferential wall of the outer collar 21. Together, O-rings 25, 26 prevent fluid from leaking between the valve-seat member 22 and the outer collar 21. Importantly, the O-ring 25 of port 251 also provides a seal between the valve-seat member 22 and the shaft 220, so that when the valve is in the fully closed position no
5 flow is permitted between passageway 24 of shaft 220 and the port 251 of the valve-seat member 22.

The advantage of this design over previous stopcock valves is that the outer diameter of the shaft 220 may be slightly less than the inner diameter of the valve-seat member 22, whereas previous stopcock valves required an interference fit between the
10 inner and outer components. It will be appreciated that the stopcock valve of the present invention may use frusto-conical-shaped members instead of cylindrical members. The interference fit of prior-art devices created a great deal of resistance when the stopcock valves were turned. The use of O-rings in the stopcock valve of the present invention avoids the need for this interference fit and the greater torque required for turning the
15 valve resulting from the interference fit. O-ring 27 prevents leaking from the space between the valve-seat member 22 and the shaft of the control wheel 20.

The valve-seat member is preferably made in a two-part molding process, wherein the rigid portion is first molded and then the softer resilient material is over-molded onto the rigid portion. Channels may be provided in the initially molded rigid portion so that
20 the resilient material may flow to all the desired locations; this results in columns of resilient material 28 connecting the areas of resilient material through these channels. The valve-seat member 22 is preferably molded separately from the rest of the cassette, and when the cassette is assembled the valve-seat member 22 is placed in the hollow defined by the outer collar 21 of the middle panel 18, and aligned so that aperture 251 lines up
25 with passageway 23. (The shape of the outer diameter of the valve-seat member 22 and the inner diameter of the outer collar 21 may be complementarily shaped so that the valve-seat member must align properly with the aperture 251 and the passageway 23 lined up.) Then, the front rigid panel 17 is ultrasonically welded (along with the rear rigid panel 16) to the middle rigid panel 18, and the valve-seat member 22 is then held in place in the
30 hollow area defined by the outer collar 21. The outer circumference of the valve-seat member 22 may be a bit smaller than the inner diameter of the outer collar 21; O-rings 25,

26 prevent fluid from flowing from the passages 77 or 23 to point 19. This design of the valve-seat member 22 avoids the need for tight tolerances in the various components of the valve 2. The control wheel's shaft 220 may be inserted into the hollow area defined by valve-seat member 22 after the rest of the valve has been assembled. The shaft 220 is
5 held in place by a lip 161 around the inner circumference of the hollow area defined by the rear rigid panel 16

When the valve 2 is fully opened, the circumferential aperture 251 is lined up with the fluid passage 24 in the shaft 220. When the valve is fully closed there is no fluid communication between the aperture 251 and the fluid passage 24. The outer
10 circumferential surface of the shaft 220 preferably includes a groove extending circumferentially around the shaft's outer circumferential wall from the terminus of the fluid passage 24 at the outer circumferential wall; the groove tapers in cross-sectional area and does not extend all the way around the outer circumference of the shaft 220. The groove provides greater control of the flow rate. FIG. 14 shows the respective locations
15 of the groove 231, which is located on the outer circumference of the shaft 220 and the circumferential aperture 251 of the valve seat member 22. As the aperture 251 rotates to the right, in the FIG. 14 perspective, the resistance to flow increases, until the groove 231 ends and the aperture 251 loses fluid communication with the groove 231, at which point flow is completely shut off through the control valve 2. As the aperture 251 rotates to the
20 left, in the FIG. 14 perspective, the resistance to flow decreases. Preferably, the groove 231 is longer than the diameter of the aperture 251, so that the flow rate may be controlled more finely.

As noted above, the cassette may be used independently of the control unit 10. When the cassette is used in this manner it is preferable that the membrane 41 rest against
25 the rigid back 59 of the pressure-conduction chamber 50 so as to minimize the volume of the conduit 36 for fluid passing through the pressure conduction chamber 50. If the membrane 41 were too flexible and the volume of the pressure-conduction chamber 50 varied widely, medical personnel would be unable to rely on a quick visual inspection of the rate of dripping in the drip chamber to indicate a steady, desired flow rate through the
30 IV line. Thus, it is desired that the structure of the membrane 41 be such that it tends to rest against wall 59 unless and until a sufficient pressure differential is created across the

diaphragm 41. This pressure differential is preferably caused by a negative gas pressure caused by the control unit 10. Although it is desired to manufacture the diaphragm 41 so that it has some tendency to rest against wall 59, it is desired to make the diaphragm 41 so floppy in the other direction so that less pressure is required to move it from its position
5 when the pressure-conduction chamber 50 is full, the "filled-chamber" position. It is also desired that the measurement gas provided by the control unit 10 against the outer face of the membrane 41 be at substantially the same pressure as the fluid on the inner side of the membrane 41 in the pressure-conduction chamber 50.

By molding the diaphragm 41 in the shape of a dome corresponding to that of the
10 rigid wall 59, the diaphragm will have a tendency to remain in its position, as shown in FIG. 5, resting against wall 59 when the chamber 50 is at its lowest volume, the "empty-chamber" position. However, when the diaphragm 41 is molded in this way, it also tends to remain in the filled-chamber position, in other words, when the diaphragm 41 is bulging convexly outward from the cassette. This convex, filled-chamber position can be
15 made unstable by adding additional material on the outer, usually concave surface of the diaphragm 41. This additional material 43 can be seen in the cross-section of a preferred embodiment of the diaphragm as shown in FIG. 15. The diaphragm 41 shown in FIG. 15 is molded in the position shown and has a tendency to remain in that position. When the chamber is filled with fluid, the normally concave side of the diaphragm becomes convex,
20 and the additional material 43 is subject to an additional amount of strain since it is at the outer radius of this convex, filled-chamber position. The diaphragm 41 shown in FIG. 15 also includes an integrally molded O-ring 44 around its circumference for mounting and sealing the diaphragm 41 in the cassette. FIG. 16 shows a view of the exterior side of the diaphragm 41 of FIG. 15. This surface of the diaphragm 41 is normally concave when the
25 diaphragm is in the empty-chamber position. The additional material 43 can be seen in the view of FIG. 16. FIG. 17 shows the interior side of the diaphragm 41 of FIG. 15. This side is normally convex when the diaphragm 41 is in the empty-chamber position. Thus, as a result of molding the diaphragm so that its inner surface has a smooth constant radius and the outer surface has additional material, which thereby interrupts the
30 smoothness and constant radius of the rest of the outer face of the diaphragm, the

diaphragm 41 has the desired tendency to remain in the empty-chamber position while being unstable in the filled-chamber position.

By positioning this additional material 43 near the outlet mouth 57 of the pressure-conduction chamber 50, the collapse of the diaphragm 41 from its filled-chamber can be
5 somewhat controlled so that the diaphragm tends to collapse first and the lower portion of the pressure-conduction chamber near the outer mouth 57 before further collapsing in the upper region of the pressure conduction chamber nearer the inlet mouth 56. The cassette is preferably mounted in the control unit with a slight tilt so that the passage 36 is vertical and the inlet mouth 56 is at the very top of the chamber 50 and the outlet mouth 57 is at
10 the very bottom of the chamber 50. This orientation permits the bubbles that may be present in the chamber 50 to gravitate towards the inlet mouth 56, which is at the top of the chamber. In a preferred method of eliminating the bubbles from the IV fluid, any bubbles that are detected by the control unit in the pressure conduction chamber 50 are forced by pressure from the control unit against the external surface of the membrane 41
15 up to the inlet mouth 56 to the cassette inlet 31 up the IV line to the fluid source, sometimes after several purging and filling cycles. When purging the bubbles from the chamber 50 through the inlet mouth 56 it is preferred that the chamber collapse at its bottom first so that the membrane does not interfere with bubbles moving upwards through the chamber 50.

20 FIGS. 18 and 19 show a preferred membrane design for the second membrane-based valve 7. This membrane has an O-ring 78 for mounting and sealing the membrane onto the cassette (like the lip 44 on the membrane 41 for the pressure-conduction chamber, and like the circular membrane, which is not shown, for the first membrane-based valve 6). This membrane has a first portion 71, which is used to seal off the mouth
25 73 located on protrusion 72 (see FIG. 5). The control unit 10 exerts a pressure against this portion of the membrane 71 mechanically, in order to close off the valve. The second portion 74 of the membrane is sufficiently compliant so that when the control valve 2 is sufficiently restricting flow out of the outlet 76 of the second membrane-based valve 7 the compliant portion 74 of the membrane will expand outwardly so as to hold under pressure
30 a volume of IV fluid. This design is desirable so that when the inlet mouth 73 is closed, because the pressure-conduction chamber needs to be refilled, the fluid stored in the

valving chamber (item 75 in FIG. 5) is available to be dispensed through the control valve 2.

FIG. 20 shows a schematic for an electrical model of the operation of the second membrane-based valve 7 working in conjunction with the stopcock-type control valve 20.

5 When the valve leading from the outlet 57 of the pressure-conduction chamber 50 is open, permitting flow from the pressure-conduction chamber through valve 7, and if the stopcock valve is set to provide a large amount of resistance to the flow from valve 7 to the patient, the valving chamber 75 and its corresponding membrane portion 74 can accumulate a "charge" of fluid, much like a capacitor, as shown in FIG. 20. When

10 membrane 71 is then urged against mouth 73 closing off flow from the pressure-conduction chamber 50, the charge of fluid in the valving chamber 75 is urged by the compliant membrane 74 to continue flow through the stopcock valve 20. As fluid exists the valving chamber 75, the pressure of the fluid decreases as the compliant portion 74 of the membrane returns to its unstretched state. FIG. 21 shows a graph depicting the

15 pressure of the IV fluid being delivered to a patient over time as outlet valve 71, 73 is closed at time t_1 and reopened at t_2 . A solid line depicts the pressure to the patient without a compliant membrane 74 design. With a compliant membrane 74, the sharp drop off in pressure at t_1 is eliminated or ameliorated. If the stopcock valve is nearly closed so that only a small trickle of fluid is allowed to flow through it the design of the compliant

20 membrane 74 will greatly smooth out the delivery of fluid, as long as the time between t_1 and t_2 is not too long. When the stopcock valve 2 is fully open a sharp drop in pressure may still be expected at time t_1 .

As noted above, when an air bubble is being purged from the pressure-conduction chamber 50, it is preferably forced up through the chamber's inlet valve 56 (which in this

25 air-elimination mode is acting as an outlet). Preferably, the inlet port 56 is shaped so that a small bubble will not tend to stick to an edge of the port while allowing liquid to flow past it. To prevent such sticking of a small bubble, the port 56 preferably flares out so that the corner where the port 56 meets the inner wall of the pressure-conduction chamber 50 is greater than 90° , making the corner less likely a place where the bubble will stick.

30 However, the mouth of the port 56 cannot be so large that liquid can easily flow by the bubble when fluid is exiting the pressure-conduction through the port 56. In order to

accomplish this, the port must be sized and shaped so that the surface tension of the IV fluid being forced upward from the pressure-conduction chamber 50 forces a bubble located at the port 56 up through the inlet valve 6. It is also preferable that the port 56 be sized and shaped so that when liquid is pulled back into the pressure-conduction chamber 50, the bubble can hover near the port as liquid passes around it. A preferred inlet port 56 shape is shown in FIGS. 22 and 23. The port's size increases from the end 57 that connects to the IV line's upper portion to the end 58 leading into the pressure-conduction chamber. FIG. 24 shows a cross-section of the inlet valve 56. It has been found that providing an inlet port to the pressure-conduction chamber with this shape improves the air-elimination system's ability to purge bubbles from the chamber. Using a port such as that shown in FIGS. 22-24 in conjunction with the membrane 41 of FIGS. 15-17 helps force bubbles more quickly out of the pressure-conduction chamber when attempting to purge the bubbles back through the cassette's inlet 31 to the IV source.

FIG. 25 shows a preferred arrangement of teeth around the circumference 29 of the control wheel 20. The teeth provide means for a gear in the control unit 10 to engage securely the control wheel's circumference--in particular, a gear that is used to prevent the free flow of fluid through the cassette when the cassette is removed from the control unit 10. When the door 102 of the control unit 10 is being opened, the gear turns the control wheel 20 to close the stopcock-type valve 2, thereby stopping all flow through the cassette and preventing free flow. To ensure that the gear does not continue turning the wheel 20 once the valve 2 has been closed off entirely, a sector 92 along the wheel's circumference is left free of teeth. When the wheel 20 is turned enough so that the gear is adjacent this toothless sector 92, the valve 2 is fully closed. The lack of teeth prevents the gear from continuing to turn the wheel; thus, the wheel cannot be turned too much.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims hereinbelow.

What is claimed is:

1. A stopcock control valve of the type having a first rigid member having a first surface, the first rigid member defining a first fluid-path portion with a first terminus at the first surface, and a second rigid member having a second surface, the second rigid member defining a second fluid-path portion with a second terminus at the second surface, wherein the first terminus includes a groove defined on the first surface, the groove tapering from a large cross-sectional area to a small cross-sectional area, and wherein the first and second rigid members are capable of being rotated with respect to each other from a fully open position continuously through partially open positions to a closed position, characterized in that:
 - the first and second surfaces define a space therebetween; and by
 - a resilient sealing member disposed in the space between the first and second surfaces and extending from the second surface to the first surface,
 - the sealing member defining an aperture through which fluid communication is provided between the first and second fluid-path portions when the first and second rigid members are in an open position with respect to each other,
 - the sealing member being sealingly mounted to the second surface so that, when the first and second rigid members are in the closed position with respect to each other, the sealing member provides a seal preventing flow between the first and second fluid-path portions,
 - the sealing member being located with respect to the groove such that, when the first and second rigid members are in a partially open position with respect to each other, fluid flowing between the first and second fluid-path portions flows through the groove as well as the sealing member's aperture; and
 - seal means disposed with respect to the space defined by the first and second surfaces for preventing flow of fluid out of the space except through the first fluid-path portion.
2. A valve according to claim 1, wherein the groove, when the first and second members are in at least one partially open position with respect to each other,

extends beyond two sides of the sealing member, so that fluid can flow through the sealing member's aperture and in two different directions in the groove.

3. A valve according to claim 1, wherein the first and second surfaces are
5 circumferential cylindrical surfaces which may be rotated with respect to each other.

4. A valve according to claim 3, wherein the first rigid member is a cylinder
and the first surface is an outer circumferential surface of the cylinder, the second rigid
member defines a cylindrical hollow area for receiving the first rigid member and the
10 second surface is an inner circumferential surface of the second member.

5. A valve according to claim 4, wherein the seal means includes an O-ring
made of resilient material disposed around the second rigid member's circumference.

15 6. A valve according to claim 5, wherein the sealing member and the O-ring
are formed from a single integral piece of resilient material.

7. A valve according to claim 6, wherein the first member is connected to a
control knob for rotating the first rigid member.

20

8. A valve according to claim 7, wherein the groove, when the first and
second members are in at least one partially open position with respect to each other,
extends beyond two sides of the sealing member, so that fluid can flow through the
sealing member's aperture and in two different directions in the groove.

25

9. A method of making a stopcock control valve comprising the steps of:
providing a first rigid member defining a first fluid-path portion;
providing a second rigid member defining a second fluid-path portion, the first and
second members having complementing surfaces, which may be moved with respect to
30 each other, each of the first and second fluid-path portions terminating at ports at the
complementing surface of the respective member, the first fluid-path portion terminating

in a groove on the first rigid member's complementing surface;

molding a resilient material about and to the second rigid member so as to form an aperture sealing member about the port on the complementing surface of the second rigid member; and

- 5 assembling the first and second rigid members so as to bring the complementing surfaces adjacent each other and so that the sealing member is urged against the complementing surface of the first rigid surface.

- 10 10. A method according to claim 9, wherein the first and second rigid members are generally cylindrical, and the step of molding a resilient material about and to the second rigid member includes forming a resilient O-ring around and to a circumference of the second rigid member.

- 15 11. An improved stopcock control valve of the type having:
an inner rigid member having an outer circumferential surface, the member defining an inner fluid-path portion with an outer terminus at the outer circumferential surface;

- an outer rigid member, which is hollow so as to receive the inner member, the outer member having an inner circumferential surface, the outer member defining an outer
20 fluid-path portion with an inner terminus at the inner circumferential surface, wherein the inner and outer members are capable of being rotated with respect to each other from an open position to a closed position, and wherein at least one of the inner and outer termini includes a groove defined on the surface of the corresponding circumferential surface, the groove tapering from a large cross-sectional area to a small cross-sectional area; and

- 25 a resilient sealing member, disposed between the inner and outer circumferential surfaces, for preventing flow between the inner and outer fluid-path portions when the inner and outer rigid members are in a closed position with respect to each other, the resilient sealing member defining an aperture for permitting flow between the inner and outer fluid-path portions when the inner and outer rigid portions are in an open position
30 with respect to each other.

12. A cassette for use in a system for controlling the flow of intravenous fluid from a source to a patient, the cassette comprising:
- a rigid housing;
 - a membrane disposed adjacent the housing, the rigid housing and the membrane defining a valving chamber, wherein a first passage enters the valving chamber at a first mouth located at the end of a protrusion of the rigid housing into the valving chamber towards the membrane, and wherein the valving chamber may prevent the flow of fluid therethrough when the membrane is forced against the first mouth; and
 - a control valve for restricting the flow of intravenous fluid from the valving chamber to the patient, the control valve being located downstream of the valving chamber and connected to the valving chamber by a second passage, which exits the valving chamber at a second mouth, wherein the membrane defining the valving chamber is large enough and resilient enough and the second mouth is positioned far enough away from the membrane so that the valving chamber may provide a supply of pressurized intravenous fluid when the first mouth is sealed closed and when there is a restriction downstream of the valving chamber.
13. A cassette according to claim 12, further including a
- a second membrane disposed adjacent the rigid housing, the rigid housing and the second membrane defining a pressure-conduction chamber, which is connected to the valving chamber by the first passage and which is located upstream of the valving chamber.
14. A cassette according to claim 13, wherein the rigid housing portion that defines the pressure-conduction chamber is generally dome-shaped, and the second membrane has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is at its smallest volume, and in which position the second membrane rests against the rigid housing and assumes the dome shape of the rigid housing, the second membrane having a structure causing the second membrane to be stable in the empty-chamber position but relatively unstable in the filled chamber

position.

15 15. A cassette according to claim 14, wherein the pressure-conduction chamber has two mouths, the first pressure-conduction chamber mouth providing fluid from the intravenous-fluid source, the second pressure-conduction chamber mouth leading to the first passage, wherein the rigid housing and the second membrane in the empty-chamber position define an unobstructed fluid passageway through the pressure-conduction chamber from the first to the second pressure-conduction chamber mouth.

10 16. A cassette according to claim 15, wherein the second membrane has a structure that causes the second membrane, when its at its full-chamber position, to collapse in the region of the second mouth before collapsing nearer the first mouth.

15 17. A cassette for use in a system for controlling the flow of intravenous fluid from a source to a patient, the cassette comprising:
 a rigid housing;
 a membrane disposed adjacent the rigid housing, the rigid housing and the membrane defining a pressure-conduction chamber, wherein the rigid housing portion that defines the pressure-conduction chamber is generally dome-shaped, and the membrane
20 has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is at its smallest volume, and in which position the membrane rests against the rigid housing and assumes the dome shape of the rigid housing, the membrane having a structure causing the membrane to be stable in the
25 empty-chamber position but relatively unstable in the filled chamber position.

 18. A cassette according to claim 17, wherein the pressure-conduction chamber has two mouths, the first pressure-conduction chamber mouth providing fluid from the intravenous-fluid source, the second pressure-conduction chamber mouth leading to the patient, wherein the rigid housing and the membrane in the empty-chamber position
30 define an unobstructed fluid passageway through the pressure-conduction chamber from

the first to the second pressure-conduction chamber mouth.

19. A cassette according to claim 18, wherein the membrane has a structure that causes the second membrane, when its at its full-chamber position, to collapse in the
5 region of the second mouth before collapsing nearer the first mouth.

20. A cassette according to claim 17, wherein the membrane has an interior surface that comes into contact with the fluid, and exterior surface, wherein the membrane is molded in its empty-chamber position with the interior surface having a smooth
10 concave dome shape corresponding to the dome shape of the rigid housing portion that defines the pressure-conduction chamber, and with the exterior surface has a generally convex dome shape, but further having some additional material to cause the membrane to be unstable in its filled-chamber position.

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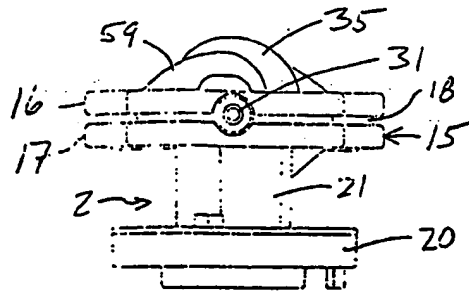


Fig. 1

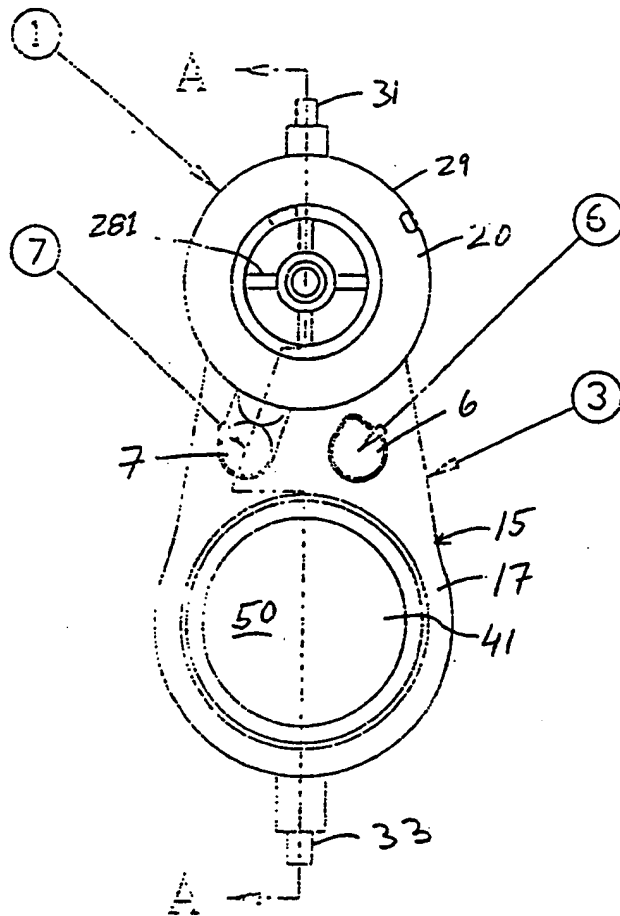


Fig. 2

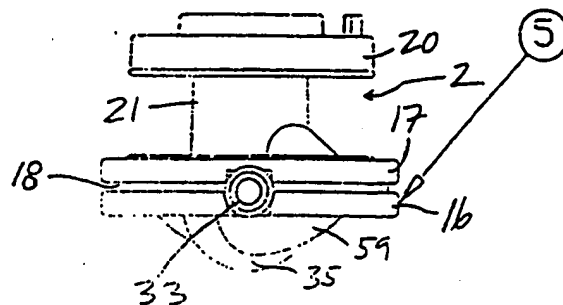


Fig. 3

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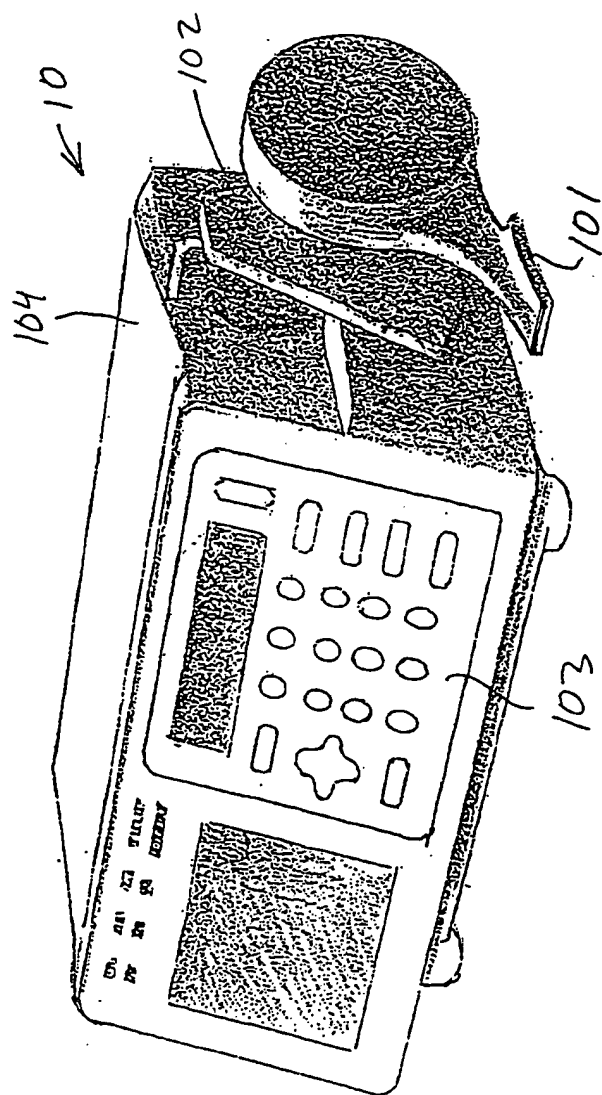
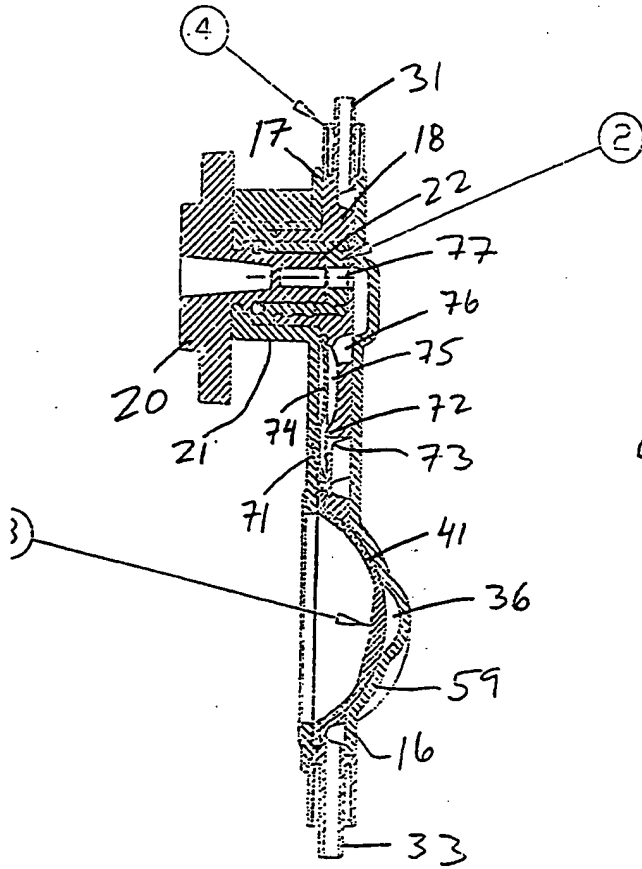


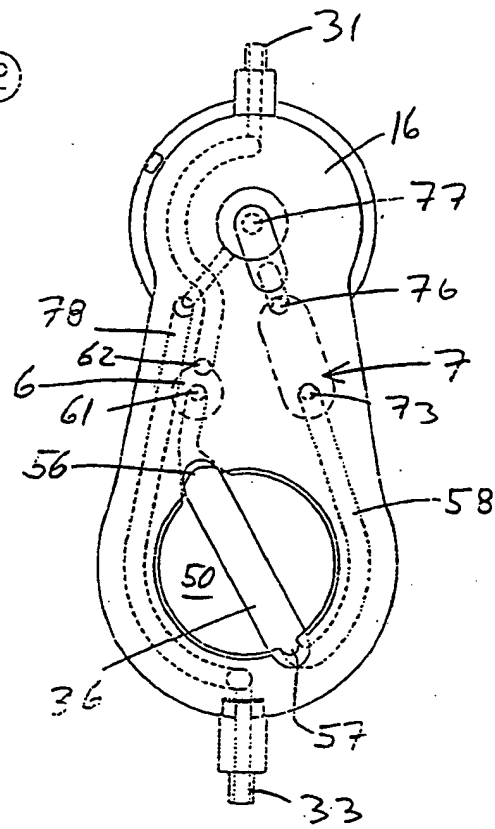
Fig. 4

Fig. 5

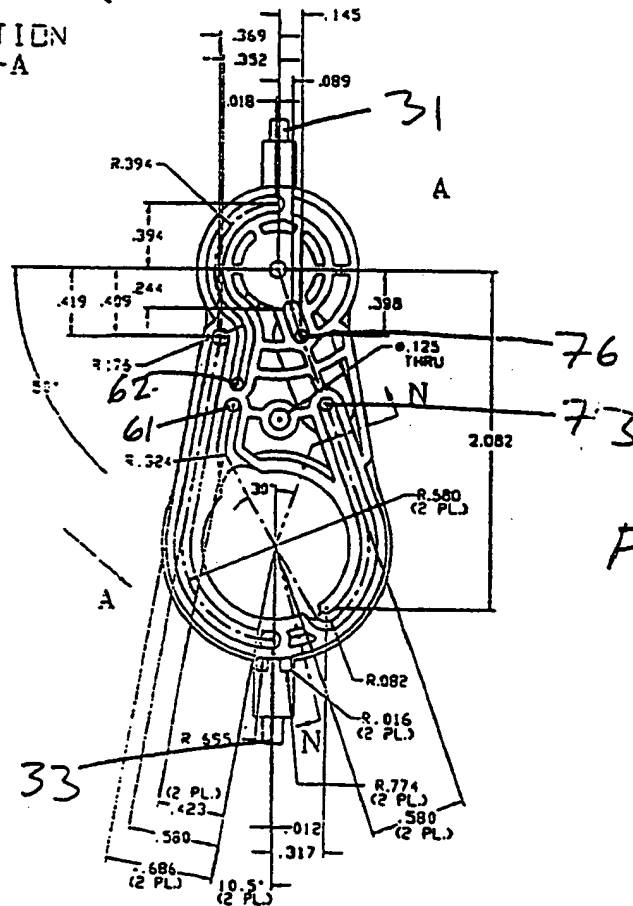
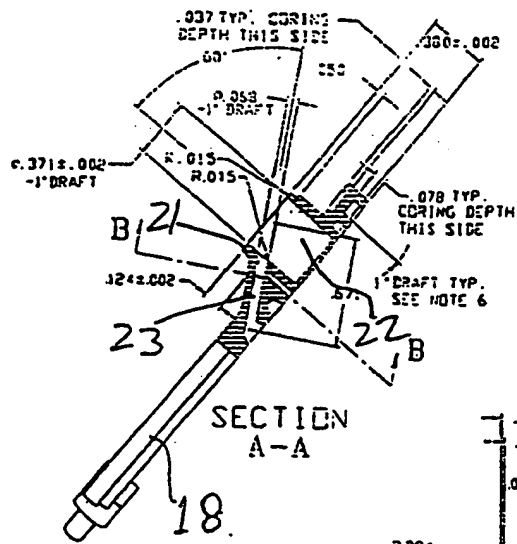


SECTION A-A

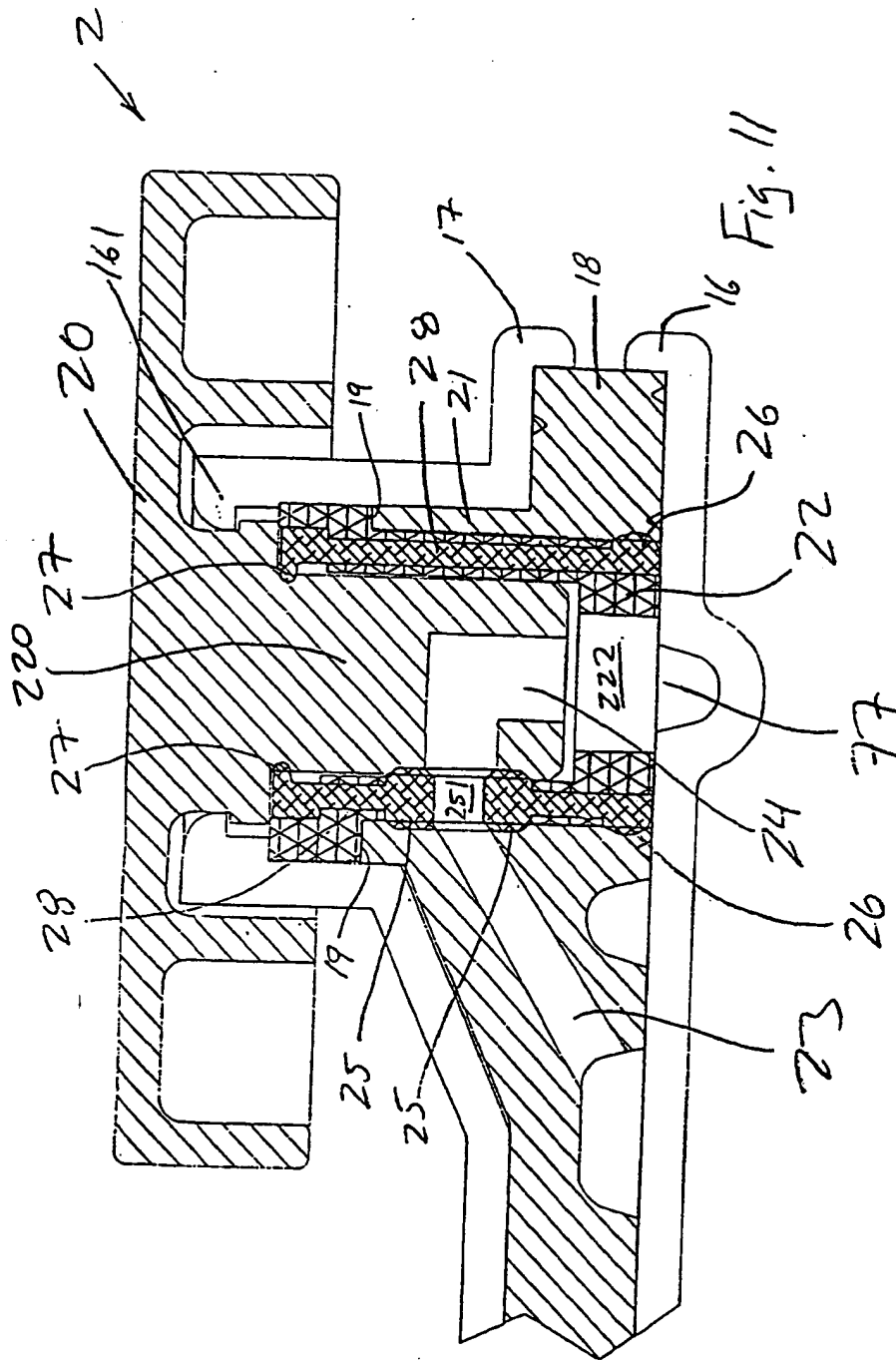
Fig. 6

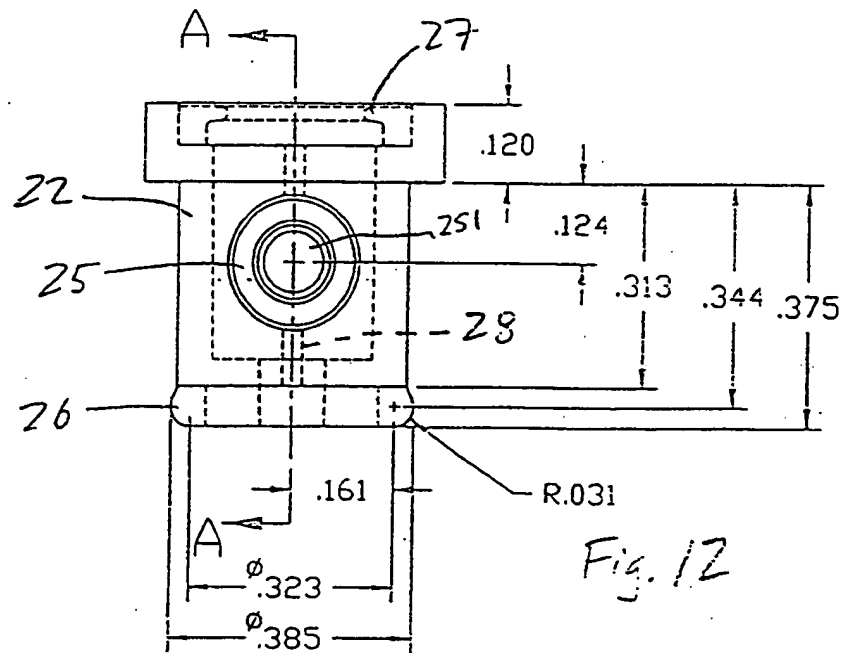


REAR VIEW SHOWING
FLUID PATHS

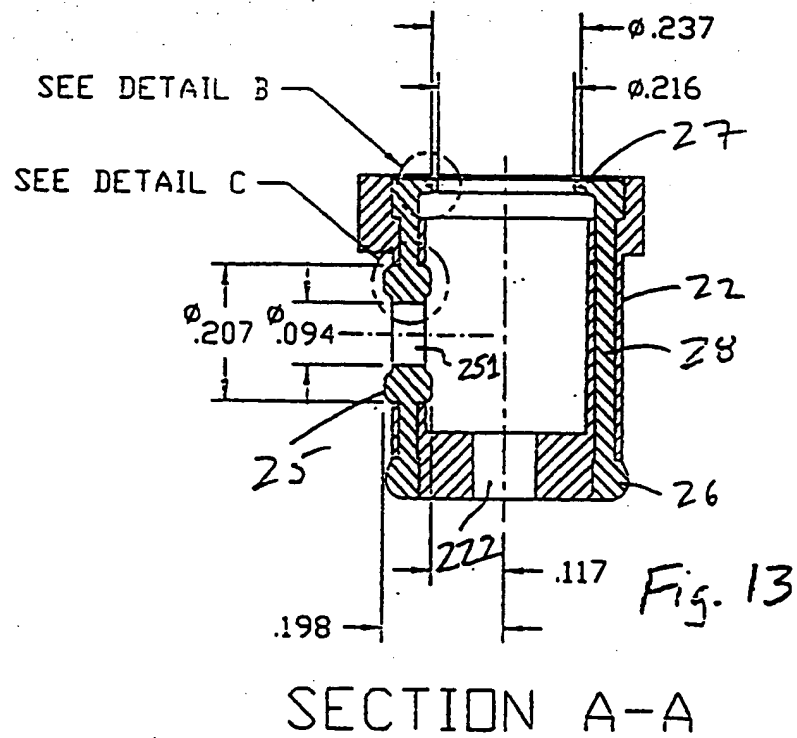


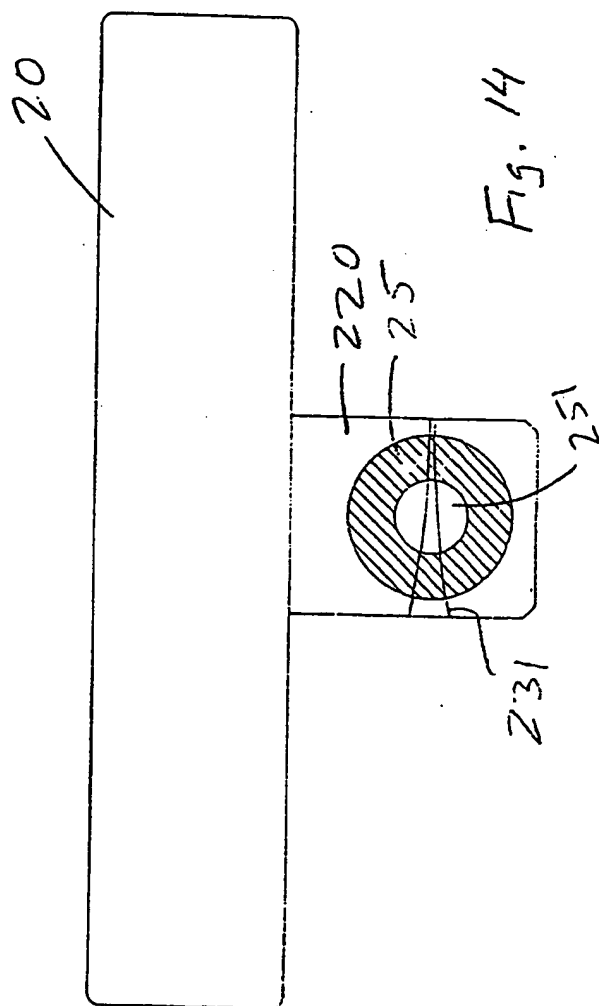
6 / 13

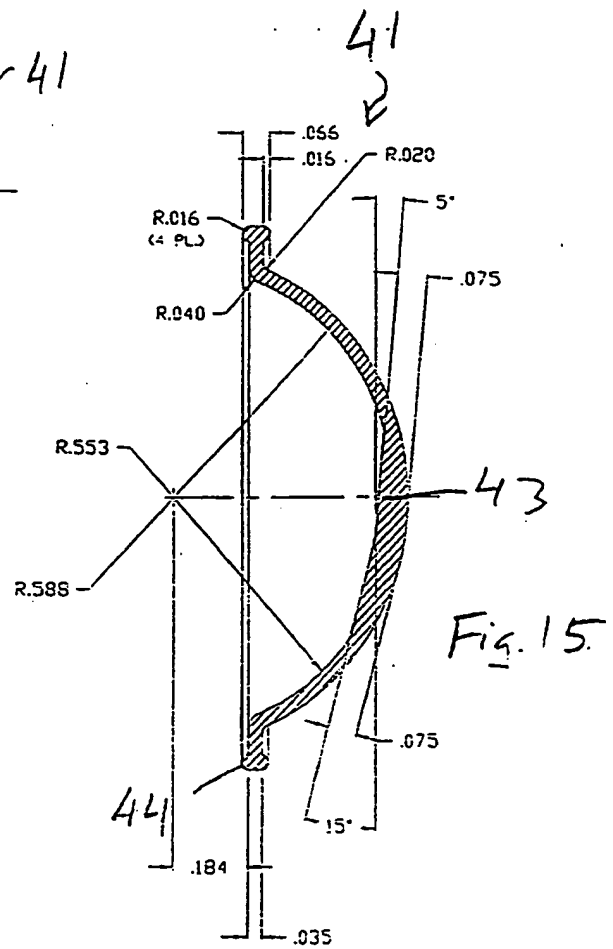
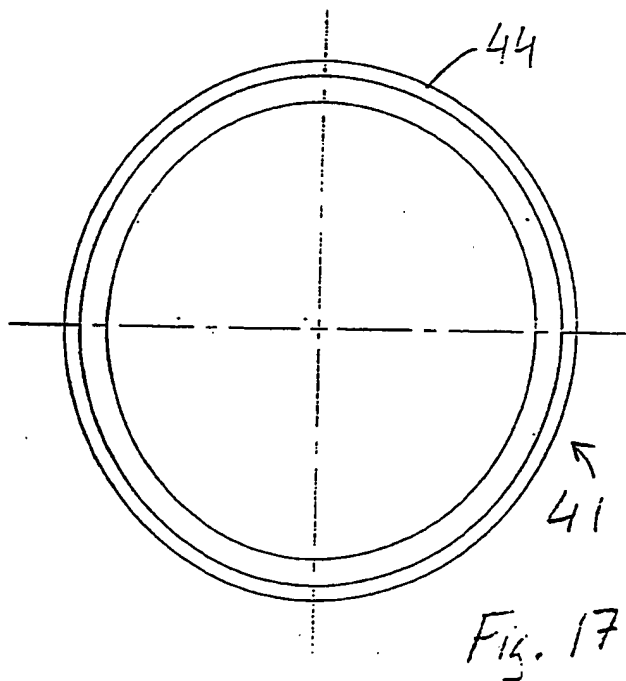
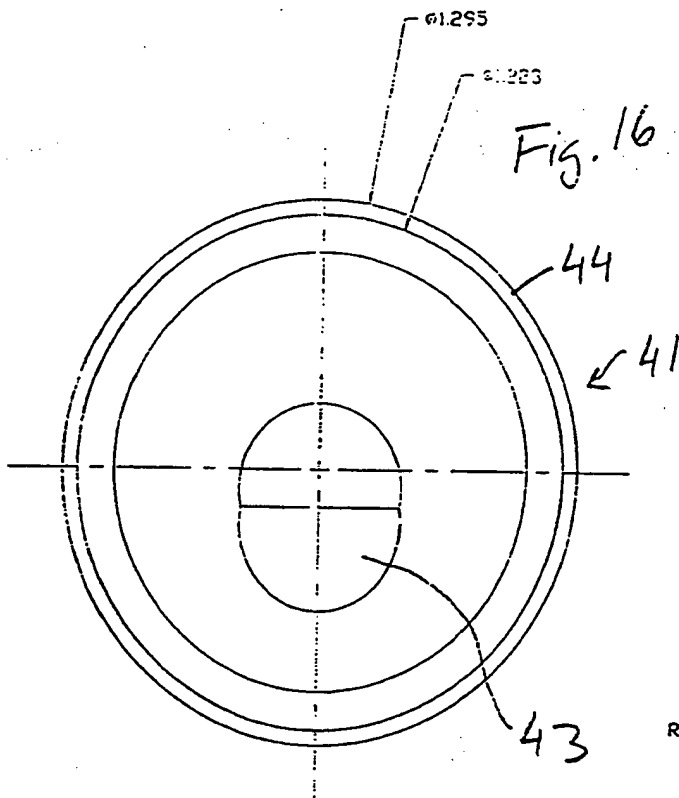




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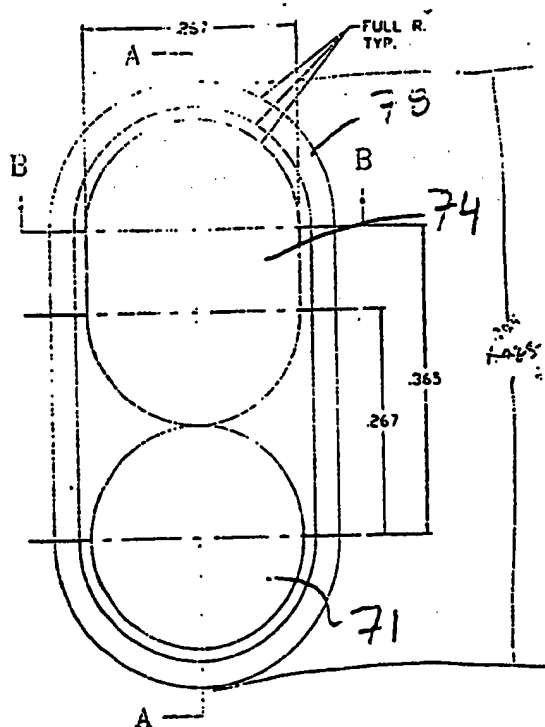


Fig. 18

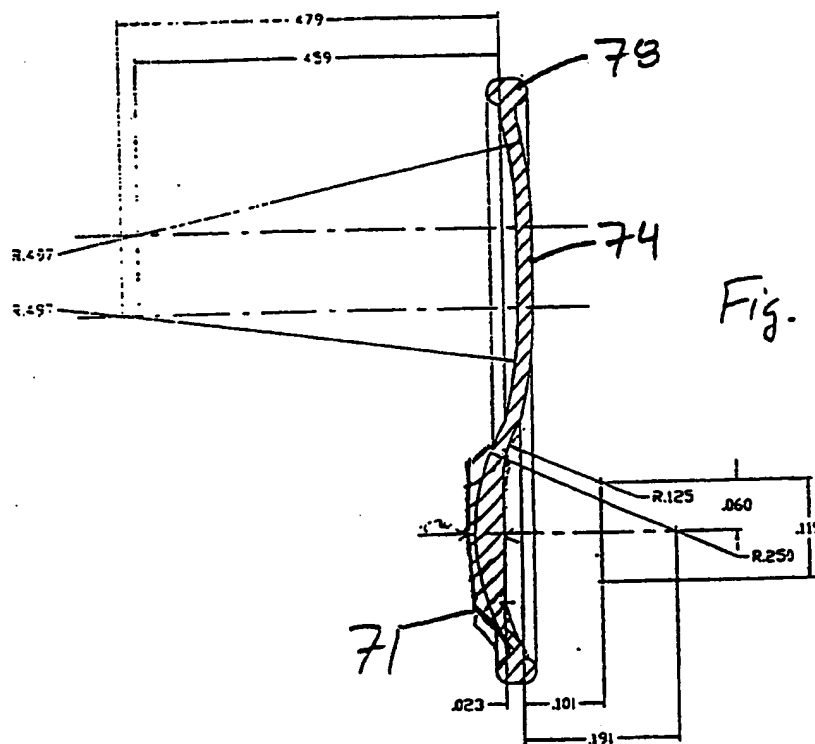


Fig. 19

SECTION A-A

Fig. 20

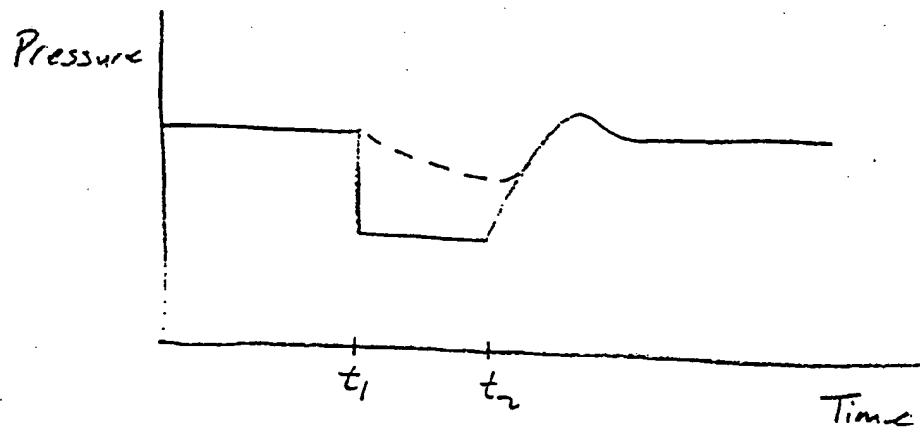
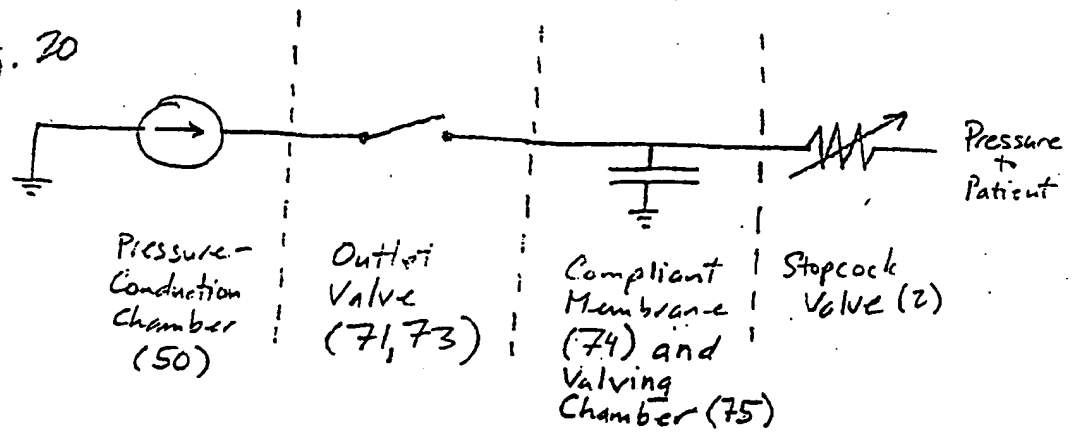
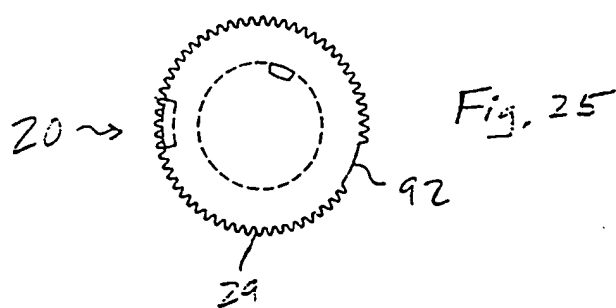
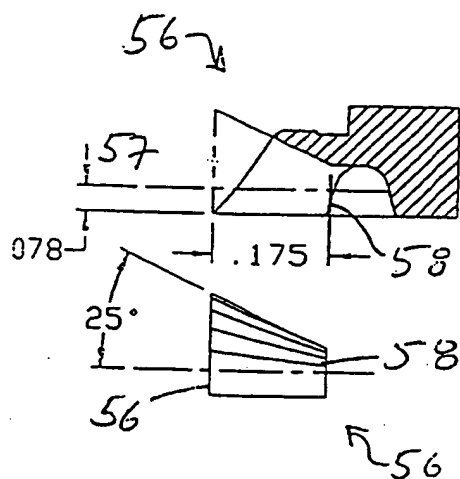
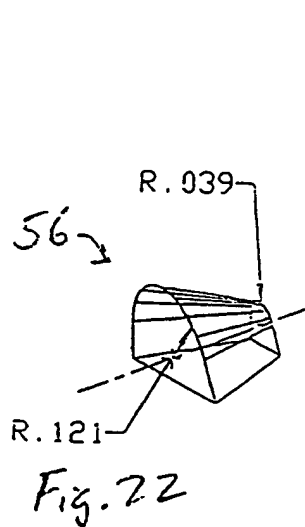


Fig. 21



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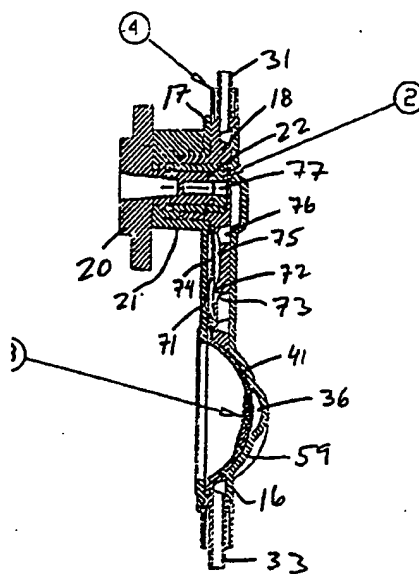
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 5/168, F16K 5/04, A61M 5/142		A3	(11) International Publication Number: WO 96/40328
			(43) International Publication Date: 19 December 1996 (19.12.96)
(21) International Application Number: PCT/US96/06622			(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 9 May 1996 (09.05.96)			
(30) Priority Data: 08/478,065 7 June 1995 (07.06.95) US			
(71) Applicant: DEKA PRODUCTS LIMITED PARTNERSHIP [US/US]; 340 Commercial Street, Manchester, NH 03101 (US).			
(72) Inventors: HOULE, Phillip, R.; 83 Bay Street, Manchester, NH 03104 (US). LARKINS, William, T.; 245 Carnegie Street, Manchester, NH 03104 (US).			
(74) Agents: SUNSTEIN, Bruce, D. et al.; Bromberg & Sunstein, 11th floor, 125 Summer Street, Boston, MA 02110-1618 (US).			Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
			(88) Date of publication of the international search report: 6 February 1997 (06.02.97)

(54) Title: CASSETTE FOR INTRAVENOUS-LINE FLOW-CONTROL SYSTEM

(57) Abstract

A cassette for controlling the flow of IV fluid from a patient to a source. The cassette preferably includes, along the fluid passage through the cassette, first and second membrane-based valves (6, 7) on either side of a pressure-conduction chamber (50), and a stopcock-type valve (20). The stopcock valve is preferably located downstream of the second membrane-based valve (7), which is preferably located downstream of the pressure-conduction chamber (50). The stopcock control valve preferably has two rigid cylindrical members (22, 220) with complementary surfaces, wherein one member includes a tapered groove (231) defined on its complementary surface. The two complementary surfaces define a space therebetween, instead of having an interference fit, and a resilient sealing member (25) is disposed in this space. When the first and second rigid members are in an open position with respect to each other, the sealing member defines an aperture (251) through which fluid communication is provided between the fluid-path portions (23, 24) defined respectively by the two rigid members. When the first and second rigid members are in the closed position with respect to each other, the sealing member provides a seal preventing flow between the fluid-path portions. The membrane defining the valving chamber of the second membrane-based valve (7) is preferably large and resilient, so that the valving chamber (75) may provide a supply of pressurized intravenous fluid to the patient, when the valve is closed and the stopcock valve provides a restriction downstream of the valve. The pressure-conduction chamber (50) preferably has a membrane (41) that is stable in the empty-chamber position but relatively unstable in the filled-chamber position.



SECTION A-A

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/06622

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/168 F16K5/04 A61M5/142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M F16K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE,C,58 977 (ADELHAID VOSS) 26 November 1890 see the whole document ---	1-8,11
X	BE,A,535 179 (L'AUXILIAIRE DE L'INDUSTRIE ET DES MINES "AUXIM") 15 February 1955 see page 1, line 10 - line 31; figures see page 2, line 4 - line 40 ---	1,3-7,11
X	FR,A,2 340 491 (MARTI PUIG JUAN) 2 September 1977 see page 2, line 27 - line 29; figures 3,7 see page 2, line 39 - page 3, line 22 ---	1-8,11
A	FR,A,2 138 617 (STANADYNE INC) 5 January 1973 see page 6, line 2 - line 34; figures 10,11 ---	1-8,11
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

21 November 1996

Date of mailing of the international search report

12.12.96

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/06622

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,4 230 300 (WILTSE HAROLD L) 28 October 1980 see abstract; figures 1-3 see column 4, line 32 - column 5, line 14 ---	1-11
A	EP,A,0 222 088 (OXIMETRIX) 20 May 1987 see abstract; figures 2,4 see column 3, line 16 - column 4, line 21 ---	1-11
X	EP,A,0 293 592 (ABBOTT LAB) 7 December 1988	12,13
Y	see abstract; figures 1-4 see column 3, line 49 - column 4, line 31 see column 7, line 29 - line 51 ---	14-16
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Y	see abstract; figures 30,32 see page 31, line 15 - page 32, line 12 ---	14-16
A	WO,A,93 23096 (ELAN MED TECH) 25 November 1993 see abstract; figures see page 4, line 7 - line 23 see page 5, line 3 - line 13 ---	12,17
A	GB,A,2 053 378 (BAXTER TRAVENOL LAB) 4 February 1981 see abstract; figure 5C see page 3, line 86 - line 123 -----	12,17

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 96/06622

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

PLEASE SEE ANNEX

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

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- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 96/ 06622

FURTHER INFORMATION CONTINUED FROM PCT/ISA/210

MULTIPLE INVENTIONS:

Subject No. 1 : Claims 1-8,11

Define a stopcock control valve having a first and second rigid member including a groove with a resilient sealing member, and method of making.

Subject No. 2 : Claims 9-10

Define a method of making a stopcock valve.

Subject No. 3 : Claims 12-16

Defining a cassette comprising a housing, a membrane defining a valving chamber and a downstream control valve.

Subject No. 4 : Claims 17-20

Define a cassette comprising a housing having a dome-shaped portion and membrane.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/06622

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		AU-A- 6951394	20-12-94
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		CA-A- 2163997	08-12-94

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP-A- 0702578	27-03-96
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